

Translation

## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference  ONF-4712PCT	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No.  PCT/JP2003/011835	International filing date ( <i>day/month/year</i> )  17 September 2003 (17.09.2003)	Priority date ( <i>day/month/year</i> )  18 September 2002 (18.09.2002)	
International Patent Classification (IPC) or national classification and IPC C07D 471/10, A61K 31/499, A61P 1/04, 1/16, 3/10, 9/00, 11/00, 11/02, 11/06, 13/12, 17/00, 17/06, 19/02, 29/00, 31/04, 31/18, 35/04, 37/02, 37/06, 37/08, 43/00, 25/00, 27/02			
Applicant  ONO PHARMACEUTICAL CO., LTD.			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
a. <input type="checkbox"/> ( <i>sent to the applicant and to the International Bureau</i> ) a total of _____ sheets, as follows:
<input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
<input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
b. <input type="checkbox"/> ( <i>sent to the International Bureau only</i> ) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
<input checked="" type="checkbox"/> Box No. I Basis of the report
<input type="checkbox"/> Box No. II Priority
<input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input checked="" type="checkbox"/> Box No. VI Certain documents cited
<input type="checkbox"/> Box No. VII Certain defects in the international application
<input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand  12 March 2004 (12.03.2004)	Date of completion of this report  14 July 2004 (14.07.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International Application No.

PCT/JP2003/011835

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:

- international search (under Rules 12.3 and 23.1(b))
- publication of the international application (under Rule 12.4)
- international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

The international application as originally filed/furnished

the description:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the claims:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the drawings:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3.  The amendments have resulted in the cancellation of:

- the description, pages \_\_\_\_\_
- the claims, Nos. \_\_\_\_\_
- the drawings, sheets/figs \_\_\_\_\_
- the sequence listing (specify): \_\_\_\_\_
- any table(s) related to sequence listing (specify): \_\_\_\_\_

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- the description, pages \_\_\_\_\_
- the claims, Nos. \_\_\_\_\_
- the drawings, sheets/figs \_\_\_\_\_
- the sequence listing (specify): \_\_\_\_\_
- any table(s) related to sequence listing (specify): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP03/11835

## Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- the entire international application.
- claim No. 33

because:

- the said international application, or the said claim No. 33 relates to the following subject matter which does not require an international preliminary examination (*specify*):

The subject matter of claim 33 relates to a method for treatment of the human body.

- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (*specify*):

- the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

- no international search report has been established for said claim No. 33

- the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form  has not been furnished

does not comply with the standard

the computer readable form  has not been furnished

does not comply with the standard

- the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

- see Supplemental Box for further details.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP03/11835

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	1-32, 34	YES
	Claims		NO
Inventive step (IS)	Claims	1-32, 34	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-32, 34	YES
	Claims		NO

**2. Citations and explanations (Rule 70.7)**

Document 1: WO, 01/40227, A1 (Ono Pharmaceutical Co., Ltd.), 01 May, 2003

Document 2: Formaggio, F. et al., "Nitroxyl peptides catalysts for enantioselective oxidations", Chemistry-A European Journal, (2002), Vol. 8, No. 1, pages 84-93.

The inventions described in claims 1-32 and 34 appear to be novel and to involve an inventive step over documents 1 and 2 cited in the ISR.

Documents 1 and 2 neither describe nor suggest crystals of (3R)-1-butyl-2,5-dioxo-3-((1R)-1-hydroxy-1-cyclohexylmethyl)-9-(4-(4-carboxyphenoxy)phenylmethyl)-1,4,9-triazaspiro[5.5]undecane hydrochloride.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP03/11835

## Box No. VI Certain documents cited

## 1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 03/35074 A1 [EX]	01.05.2003	18.03.2002	23.10.2001
WO 02/74770 A1 [EX]	26.09.2002	18.03.2002	19.03.2001
WO 02/74769 A1 [EX]	26.09.2002	18.03.2002	19.03.2001

## 2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)